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mammal an anti-microbial agent having anti-*Chlamydia pneumoniae* activity, wherein said anti-microbial agent inhibits infection of cells or inhibits growth or replication of said *C. pneumoniae* in said mammal, said method further comprising administering to said patient an anti-inflammatory agent, thereby treating said Alzheimer's disease.

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REMARKS

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Claims 1-30 are pending in the present application. In response to Applicants' election without traverse of Group I claims 1-17 (Paper No. 5), claims 18-30 of Group II have been withdrawn from further consideration by the Examiner as being drawn to a non-elected invention.

Claim 8 has been amended herein to include treating Alzheimer's disease in a mammal "having a *Chlamydia pneumoniae* infection." This recitation has also been added to claim 15 such that the claim recites treating Alzheimer's disease in a human patient "having a *Chlamydia pneumoniae* infection." This addition to the claims is supported throughout the specification, for example on page 17, at lines 17-25, on page 22, at lines 11-17, and in Examples 1-4. Thus, this amendment does not constitute new matter.

Rejection of Claims 8-17 Pursuant to 35 U.S.C §112, first paragraph

The Examiner has rejected claims 8-17 as being non-enabled. In the Examiner's view, the specification does not reasonably provide enablement for the treatment of Alzheimer's disease in a mammal or human patient which is not infected with *Chlamydia pneumoniae*. The amended independent claims 8 and 15 recite treatment of Alzheimer's disease in a mammal or human patient infected with *Chlamydia pneumoniae*. Thus, the rejection of claims 8 and 15 and claims dependent therefrom is no longer applicable. Reconsideration and withdrawal of the rejection of claims 8-17 pursuant to 35 U.S.C §112, first paragraph, is respectfully requested.

Rejection of Claims 1-7 Pursuant to either 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-7 as being anticipated by or, in the alternative, obvious in view of U.S. Patent No. 5,424,187 ("Shor"). Applicants respectfully traverse this rejection for the reasons given below.

Claims 1-7 recite a method of treating a *Chlamydia pneumoniae* infection in the central nervous system (CNS). The disclosure of Shor nowhere describes the treatment of a *Chlamydia pneumoniae* infection in the CNS using a macrolide antibiotic. This reference cannot

anticipate the rejected claims as the reference fails to disclose each and every element of the claims. Applicants respectfully suggest that the rejection of claims 1-7 pursuant to 35 U.S.C. § 102(b) is therefore unfounded and should be withdrawn.

With respect to the rejection of claims 1-7 pursuant to 35 U.S.C. § 103(a) as being obvious in view of Shor, the Applicants respectfully submit that the three-prong test which must be met for a reference or a combination of references to establish a *prima facie* case of obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP § 2142.

As noted above, Shor describes the use of a macrolide antibiotic to treat a *Chlamydia pneumoniae* infection, but does not disclose treatment of such an infection in the CNS, as is recited in the rejected claims. Therefore, the cited reference fails to teach or suggest all of the claim limitations.

It should further be noted that within the art of pharmacokinetics, it is well known that the efficiency with which any drug is able cross the blood-brain barrier has a significant impact on its therapeutic application to the CNS, and can be heavily dependent on any one of a number of factors, including drug formulation and routes of administration. For these reasons, parameters controlling the administration of an antibiotic for effective treatment of a non-CNS infection in an animal cannot be predicted to be straightforwardly modified to produce successful treatment of a CNS infection of an animal by the same organism, as an inefficient interaction of the antibiotic with the blood-barrier may make it necessary to fundamentally modify the antibiotic formulation or other parameters to obtain the desired therapeutic outcome in the CNS. Thus, the disclosure of Shor, which only includes treating *Chlamydia pneumoniae* infections in non-CNS parts of the body, offers little or no predictive value, even to a skilled artisan, in identifying parameters necessary for the successful treatment of *Chlamydia pneumoniae* infections of the CNS. Shor is therefore unable to render obvious the treatment of a *Chlamydia pneumoniae* infection in the CNS because this disclosure does not teach or suggest

either the treatment of these infections in the CNS or any reasonable success with such a treatment.

Because the reference cited by the Examiner omits any disclosure of treating *Chlamydia pneumoniae* infections of the CNS, it not only fails to teach or suggest all of the claim limitations, but also, cannot be considered suggestive of either modifying the treatment of non-CNS *Chlamydia pneumoniae* infections to treat *Chlamydia pneumoniae* infections of the CNS, or of any reasonable success in attempting treatment of a CNS infection. The Applicant's respectfully suggest that the Examiner has failed to meet any of the criteria for supporting a *prima facie* case of obviousness, and that the rejection of claims 1-7 pursuant to 35 U.S.C. § 103(a) is therefore improper. Reconsideration and withdrawal of this rejection is respectfully requested.

Summary

For the foregoing reasons, the Applicants respectfully contend that each of claims 1-17 is in condition for allowance. Reconsideration and withdrawal of the Examiner's rejections and allowance of claims 1-17 is respectfully requested at the earliest possible time.

Respectfully submitted,

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